DETAILED ACTION

Specification

The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: Applicant's "means for engaging" is not explicitly or implicitly spelled out in the specification as to what elements are included with the means and which are not. Applicant has previously used the phrase "means for electrically and mechanically coupling" (see paragraph [0007] which appears to cover the mere sandwiching of the conductor between in the inner an outer electrodes. (see paragraph [0038]. However, "means for engaging" are never discussed in the specification. applicant cites in his arguments, passages that describe figure 5 with a stepped portion forming an inner electrode outer surface. It is unclear whether or not applicant may be attempting to limiting the claim to the embodiment with the stepped portion or not Applicant does not point to any other embodiments that may read upon the language and for purposes of examination it is important for the examiner to identically know what applicant intends to cover. Other embodiments as well as the prior art do not provide for "damaged" outer electrode surfaces but raises the question if "coupling" by sandwiching and "engaging" are meant to mean the same thing or not. From applicant's arguments it appears for it to mean something different but has questionable support for invoking such since engaging of the components is not discussed in the original specification. Not withstanding, it is unclear what would constitute a "damaged" surface since such a term seems to be a matter of opinion. In the passages cited by applicant, it is unclear if

a distinction between "engaging" and "welding" is being made since the term "engaging" is never used. The stepped portion engages the outer electrode with or without a weld at one end or both ends.

Therefore the examiner requires the applicant to amend the specification to particularly identify all of the structure in the specification that corresponds to the "means for engaging" structure. The examiner notes that such authority can be found in MPEP 2181. page 2100-240.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

Claims 1-3, 6-12, 26-28, 30-38, 40-43 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The scope of applicant's "means for engaging" is unclear concerning claim 7 and it's dependent claims.

Claim 1 has a lack of antecedent basis for the outer conductor and inner conductor at line 13 of the claim. It is believed applicant meant to state "outer electrode" and "inner electrode".

Claims 8, 9 and 35 have a lack of antecedent basis for the "means for electrically and mechanically coupling".

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-3, 6-12, 27, 30-38, 40-43 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Ufford et al USPN 4,328,812 alone or in view either of Muench USPN 3,769,984 or Swoyer et al. USPN 6,026,567.

Ufford show an outer insulative body 12, a coiled conductor 38, an inner electrode 32 (note metal crosshatching in figure), an outer electrode 10 engaged with the inner electrode generally at 22.1 with the front surface of the outer electrode being part of the inner surface and at mechanical weld (column 3 lines 49 to 54). The outer electrode extends over the inner electrode and isolates the coiled conductor from the

inner sheath. Note stepped portion where the coil abuts the front end of the inner electrode. Since the outer electrode may be compressed on to the coil, the coil electrode, if it had insulation, may be crushed as a result as described in applicant's specification @ paragraph [0047]. Thus the outer surface of the inner electrode and the outer electrode inner surface have insulation disruption features in it malleability and ability to crush the insulation. Alternatively to have include a gripping threaded surface as in Swoyer (element 114) would have been an obvious substitution and or inclusion since Ufford et al is concerned with the coil pulling out of the welded portion. With respect to claim 7, the stepped portion of the inner electrode is considered to be one means for engaging (consistent with applicant's cited passage) and the mechanical weld is considered to be another means for engaging. Although the outer electrode may be deformed during compression to generate the weld, the process is intentional and thus the electrode is not considered to be damaged.

It is unclear as to whether other forms of welding in applicant's product by process claims such as magnetic swaging result in a different type of weld than the mechanical weld of Ufford et al USPN 4,328,812. If a distinction can be made, the examiner still considers the use of an additional weld to further secure the outer electrode in place as to be obvious. Additionally, the location of the welds (inner electrode versus outer electrode) may be inherent to the swaging process and otherwise considered obvious to hold the coil on to the inner electrode member before the mechanical swaging. Alternatively, to have used welding of a stripped, insulation free, coil distal end instead of crimping would have been obvious (See Meunch '984

column 3 lines 35-40). Applicant's product by process claims regarding a chemical treatment process may or may not result in a transformation of the outer electrode surface. To this extent no discernible structure is necessary for the claim. In addition, the cleaning and sterilization of the lead is inherent since the device will be placed in the body.

The weld formed by crushing or my x-ray diagnostics would be visible. The outer electrode retains its shape and thus is a shape memory material. Otherwise using austenitic, martensitic type shape memory alloys are well known.

Claims 26, 28, 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ufford et al USPN 4,328,812 alone or in view of Muench USPN 3,769,984. Applicant's various features such as coatings and adhesives are well known inclusions.

Claims 1-3, 6-12, 27, 30-38, 40-43 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Bornzin USPN 4,502,492 alone or alternatively in view of Ufford et al USPN 4,328,812 or Muench USPN 3,769,984 and/or or Swoyer et al. USPN 6,026,567.

Bornzin is interpreted in a similar manner as Ufford et al noting inner electrode 48 and outer electrode 46. The prior art of record as well as Webster's dictionary indicates a "weld" may be formed by compression. If not inherent, it would have been obvious to form a mechanical weld as in Ufford or an electrical weld in view of Muench.. Despite the crimping shown in the figures at reference numeral 50, the electrode surface is

deformed, but not damaged. The step formed on the inner electrode forms applicant's engagement means. Alternatively, to have provided a threaded structure such as means for engaging element 114 of Swoyer as well as a disruption feature to meet applicant's claim language would have been obvious. Bornzin uses a coating of Uridium or titanium alloys. The oxide versions being well known for medical electrodes.

Claims 26, 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bornzin USPN 4,502,492 alone or alternatively in view of Ufford et al USPN 4,328,812 or Muench USPN 3,769,984 and/or Swoyer et al. USPN 6,026,567. To have used adhesives to secure the outer insulation to the coil to prevent stretching and wear and tear would have been a well known inclusion.

Response to Arguments

Applicant's arguments filed 1-9-2008 have been fully considered but they are not persuasive. Applicant's "means for engaging" which includes the ambiguous negative limitation of "without damage" provides not concrete structure to define over the prior art of record as noted above.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark W. Bockelman whose telephone number is (571) 272-4941. The examiner can normally be reached on Monday - Friday 8:00 - 4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Carl Layno can be reached on (571) 272 -4949. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Mark W Bockelman/
Primary Examiner, Art Unit 3766
July 2, 2008